IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

CARMEN PURL, M.D., et al.

Plaintiffs,

vs.

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES, et al.,

Defendants.

No.: 2:24-cv-228-Z

AMICUS BRIEF OF AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS AND SOCIETY FOR MATERNAL-FETAL MEDICINE

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STATEMENT OF INTEREST OF AMICI CURIAE[1]

This proceeding involves a dispute over the construction and legitimacy of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") 2000 Privacy Rule and the 2024 Final Rule. As this Statement and the brief reveal, these rules were properly enacted by the United States Department of Health and Human Services ("HHS") after lengthy consideration and public comment from the medical industry and other stakeholders to facilitate the transfer of paper to electronic records. The goal was to accomplish a balance between protecting the private health information ("PHI") of all patients, while also permitting sharing of information under select and regulated circumstances in furtherance of public health.

As set forth in the accompanying Motion for Leave, Amici are preeminent organizations representing healthcare providers who have a direct stake in the issues raised by these injunctive proceedings. Amici play a critical role in the United States health care industry and are directly involved in patient care and treatment as impacted by the HIPAA Privacy Rules. On behalf of their members, Amici conduct critical research, create community, and provide guidance regarding clinical care. Amici file this brief because they have a strong and abiding interest in ensuring that all PHI is both protected and utilized appropriately in furtherance of public health.

Most critically, if this Court should invalidate the HIPAA Privacy Rule or the 2024 Final Rule, the health care industry at large would be left to navigate a patchwork of state consumer privacy laws, many of which refer to, rely on, or contain carve outs for HIPAA-regulated PHI.[2] For multiple reasons outlined in the accompanying brief, the medical community and the American

[1] No counsel for a party authored this brief in whole or in part, and no entity or person, other than amici curiae, their members, and their counsel, made a monetary contribution intended to fund the preparation or submission of this brief.

[2] *See, e.g.*, Tex. Bus. & Com. Code Ann. 541.001 et seq.; Maryland Online Data Privacy Act of 2024 (HB 567).

people need an overarching federal standard. Without the controlled sharing of PHI permitted and governed by the federal rules at issue, patient care will be adversely impacted, and medical research and innovation will be stifled.

Amici submit this brief to explain in further detail how the 2000 and 2024 HIPAA Privacy Rules arose, how they function in practice, and what would be left if they did not exist. Amici strongly believe this context is important and should be considered in evaluating the private and public implications of the relief sought by Plaintiffs.

DESCRIPTION OF AMICI CURIAE

Amici represent a diverse array of the country's largest medical associations and health care providers.

American College of Obstetricians and Gynecologists ("ACOG") is the nation's leading group of physicians providing health care for women. Representing more than 90% of board-certified OB/GYNs in the United States, ACOG is the nation's premier professional membership organization for obstetrician-gynecologists dedicated to access evidence-based, high-quality, safe, and equitable obstetric and gynecologic care. ACOG maintains the highest standards of clinical practice and continuing education of its members, promotes patient education, and increases awareness among its members and the public of changing issues facing women's health care. With more than 62,000 members, ACOG advocates for quality health care for women, maintains the highest standards of clinical practice and continuing education of its members, promotes patient education, and increases awareness among its members and the public of the changing issues facing women's health care. ACOG is committed to ensuring access to the full spectrum of evidence-based quality health care, including reproductive health care. ACOG has appeared as amicus curiae in courts throughout the country. ACOG's briefs and medical practice guidelines

have been cited by numerous authorities as a leading provider of authoritative scientific data regarding childbirth and reproductive health.

Society for Maternal-Fetal Medicine ("SMFM") is the medical professional society for maternal-fetal medicine subspecialists, who are obstetricians with additional training in high-risk pregnancies. SMFM was founded in 1977, and it represents more than 7,000 members caring for high-risk pregnant people. SMFM provides education, promotes research, and engages in advocacy to advance optimal and equitable perinatal outcomes for all people who desire and experience pregnancy. SMFM and its members are dedicated to ensuring that all medically appropriate treatment options are available for individuals experiencing high-risk pregnancies. SMFM's amicus briefs also have been cited by many courts.

INTRODUCTION

Plaintiffs challenge the validity of a final rule issued by the United States Department of Health and Human Services ("HHS") on April 26, 2024 (the "2024 Final Rule"), which amends existing HHS regulations first promulgated in 2000 (known as the "Privacy Rule") to implement certain aspects of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). Specifically, the 2024 Final Rule incorporates additional privacy protections for a specific, defined category of protected health information ("PHI") (i.e., individually identifiable health information, in any form or medium) relating to an individual's reproductive health care. Although this matter implicates only the 2024 Final Rule, Amici address both rules in response to the Court's request for a discussion of the constitutionality of the Privacy Rule and to highlight the importance of both rules to patients, their health care providers, and the health care industry at large across the United States.

To begin with, HIPAA and the resulting Privacy Rule were implemented in response to the health care industry's transition from paper to electronic medical records and a recognition of the need to provide a national standardized framework to facilitate electronic sharing of health information while also protecting against the resulting vulnerabilities to the availability, integrity, and confidentiality of health information. As further described below, the Privacy Rule sets the federal floor for health privacy protections and establishes national standards governing how PHI can generally be shared between regulated health care providers, health plans, and health care clearinghouses ("Covered Entities"), as well as with government agencies and other actors within the health care industry. The Privacy Rule generally limits permitted uses and disclosures of PHI without written individual authorization to uses and disclosures for treatment, payment, and health care operations of a Covered Entity; however, there are several other permissions to accommodate

uses and disclosures for the benefit of public health and safety, as well as the activities of government agencies.

And through the Privacy Rule and other HIPAA-implementing regulations, HHS has established a consistent and reliable framework for the industry and patients alike; one that is capable of accommodating technological advancements and other consistently evolving changes to our health care delivery system. These regulations not only set a nationwide floor for protecting PHI, but also provide a mechanism by which information can be shared in furtherance of critical medical research and innovation. In combination, these protections and information sharing features strengthen public health and help establish the United States to be a world leader in the field of medicine.

Finally, the Privacy Rule, including the amendments implemented under the 2024 Final Rule, is the product of HHS's considered evaluation, relying on input from the health care industry and information technology experts over the course of nearly three decades. Both the original Privacy Rule and the 2024 Final Rule reflect HHS's efforts to balance the individual's interest in protecting the privacy of highly sensitive health information with other important interests, including efficient health care delivery, clinical research, innovation and advancement in medicine, public health, health agency oversight, and law enforcement activities. Both rules further illustrate HHS's understanding that these interests may at times conflict, with one overtaking the other in terms of priority, depending on the circumstances.

In particular, the 2024 Final Rule specifically reflects the long-standing recognition within the health care industry and among affected individuals within this country that, irrespective of

political affiliation or religious ideology, reproductive health care[3] is intrinsically personal and highly confidential. This manifestly sensitive information warrants a heightened level of protection, similar to that which has been applied to other special categories of information (e.g., substance use disorder and mental health records). Importantly for this proceeding, however, the 2024 Final Rule explicitly limits these heightened protections to reproductive health care that is ***lawful*** in the state in which it is provided, thereby acknowledging that the Privacy Rule, as amended by the 2024 Final Rule, should not be used as a shield for illegal conduct or a sword to engage in invasive inquiries into a citizen's access to reproductive healthcare. *See* 42 C.F.R. § 164.502(a)(5)(iii)(B).

Given this express exception, there is every reason to question Plaintiffs' contention that HHS promulgated the 2024 Final Rule to "obstruct States' ability to enforce their laws regulating abortion" and other reproductive health care.[4] To the contrary, the 2024 Final Rule is intended to accommodate investigations of illegal activity by state law enforcement authorities with a demonstrable law-enforcement basis. By the same token, the changes promulgated by the 2024 Final Rule also provide for state action within state lines and restricts states from the unauthorized extra-jurisdictional enforcement of their laws, thereby preserving state autonomy in the establishment of laws governing reproductive health care. In this regard, the 2024 Final Rule ***aligns directly*** with the United States Supreme Court's decision in *Dobbs v. Jackson Women's Health Org.*, and its recognition of the state's role in the regulation of reproductive health care. 597 U.S. 215, 142 S. Ct. 2228 (2022).

[3] "Reproductive health care means health care, as defined in this section, that affects the health of an individual in all matters relating to the reproductive system and to its functions and processes." 45 C.F.R. § 106.103 (2024).

[4] ECF 1 (Complaint at ¶ 42).

In response and consistent with its statutory mandate, HHS promulgated the 2024 Final Rule to provide necessary clarification of privacy standards and requirements to accommodate changes in the delivery of reproductive health care in the United States. The 2024 Final Rule is a product of over 30,000 comments from various industry stakeholders, including, among others, legal, clinical, and technological experts, and patients. Some 42 individual states and Washington D.C. provided input as well. Just as with the original Privacy Rule, the 2024 Final Rule is intended to provide a consistent and reliable framework for the sharing and protection of reproductive health care information, even in an evolving state law landscape. That framework, in turn, provides a necessary degree of certainty for how this sensitive health information must be handled with corresponding benefits enabling greater access to critical health care services, promoting trust and effective communication between patients and their health care providers, and facilitating the flow of information within our national health care system — all of which are pivotal for the United States to remain a world leader in health care delivery and medical and scientific innovation.

If successful, the efforts to invalidate the 2024 Final Rule, or more broadly, the Privacy Rule itself, will upend national health care privacy law and cause confusion for health care providers, health plans, clinical researchers, and patients alike. In particular, such a move would eliminate the uniform and minimum privacy protections now available to patients. Such a move likewise would leave clinicians with the difficult task of deciphering the complicated patchwork of state privacy laws. Further, essential medical research that relies on the consistent sharing of patient information would be stifled, ultimately impacting medical innovation and the public health. Yet, medical research is undeniably essential for developing new treatments for diseases and for determining the causes of diseases in order to prevent them from occurring in the first

place.[5] Without the sharing of PHI under the guidance of the HIPAA Privacy Rule, researchers cannot establish causative links, determine which treatments are most appropriate for certain types of patients, or develop new drugs or therapies that effectively treat medical conditions.

When dealing with complex and sensitive issues of medical privacy, care and interrelated delivery systems, it is essential to take into account how the information currently governed by HIPAA is maintained, shared, and used. Only then can an informed decision be made on the nuanced question of how to best protect private and sensitive health care information, while at the same time serving the needs of the medical profession, state interests and patient welfare.

ARGUMENT

I. HIPAA IS THE PRODUCT OF SUBSTANTIAL AND CONSIDERED LEGISLATIVE AND REGULATORY COLLABORATION

A. Congress Delegated the Power to Enact HIPAA to the Department for Health and Human Services

HIPAA was enacted in 1996 based on broad bipartisan support and with the express intent of empowering the HHS Secretary to establish standards for the electronic exchange, privacy, and security of health information.[6] Congress recognized the need for protection of health information privacy generally, and the privacy implications of electronic data in particular. Indeed, numerous bills preceding HIPAA's enactment laid bare the need for a comprehensive national health privacy law to provide a minimum level of protection for individuals. Senator Robert Bennett (R-UT) commented directly on this issue, stating:

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[5] *See, e.g.*, *Importance of Medical Research*, VOYAGE MEDICAL, https://voyagemedical.com/importance-of-medical-research/ (last visited Mar. 6, 2025).

[6] *See* Off. of Civ. Rts., *Summary of the HIPAA Privacy Rule*, U.S. DEP'T OF HEALTH AND HUMAN SERVS. ("HHS"), https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html#:~:text=The%20Health%20Insurance%20Portability%20and%20Accountability%20Act%20of%201996%20(HIPAA,and%20security%20of%20health%20information (Oct. 19, 2022).

> Most individuals wrongly assume that their personal health information is protected under federal law. It is not. Federal law protects the confidentiality of our video rental records, and federal law ensures us access to information about us such as our credit history. However, there is no current federal law which will protect the confidentiality of our medical information and ensure us access to our own medical information. This is a circumstance that must change.[7]

The House Ways and Means Committee similarly identified the need for standards relating to the privacy of individually identifiable health information, noting:

> This section further directs the Secretary to adopt standards relating to the privacy of individually identifiable health information concerning the rights of individuals who are the subject of such information, the procedures for exercising such rights, and the authorized uses and disclosures of such information. Protecting the privacy of individuals is paramount. However, the Committee recognizes that certain uses of individually identifiable information are appropriate, and do not compromise the privacy of an individual. Examples of such use of information include the transfer of information when making referrals from primary care to specialty care, and the transfer of information from a health plan to an organization for the sole purpose of conducting health care-related research. As health care plans and providers continue to focus on outcomes research and innovation, it is important that the exchange and aggregate use of health care research be allowed.[8]

As these comments reflect, Congress needed to strike a balance between public health and research and the protection individual patient privacy. HIPAA addressed that issue.

If Congress did not enact legislation within three years of HIPAA's passage, it directed the Secretary to issue privacy regulations governing individually identifiable health information addressing, at a minimum: (i) the rights that should be granted to individuals who are the subject of individually identifiable health information; (ii) the procedures that should be established for the exercise of such rights; and (iii) the uses and disclosure of such information that should be authorized or required.[9] After Congress declined within that three-year period, as Congress envisioned, HHS took up the relevant issues. It developed a proposed rule, which it released for

[7] S. 2609, 105th Cong., 144 CONG. REC. S12174 (1998) (enacted).

[8] H.R. REP. NO. 104-496, pt. 1, at 100 (1996).

[9] *Id*. at Sec. 264(b)

public comment on November 3, 1999.[10] After receiving over 52,000 public comments, the final regulation, referred to as the "Privacy Rule," was published on December 28, 2000.[11] In March 2002, HHS proposed modifications to the Privacy Rule, again subject to public notice and comment. Another 11,000 comments were received, and the modifications were published in final form on August 14, 2002.[12]

The Privacy Rule, including as amended by the 2024 Final Rule, outlines standards that clearly fall within the specifically enumerated categories under HIPAA:

> (i) Standards for the rights of individuals who are the subject of the individually identifiable information (e.g., rights of privacy of, access to, and amendment of PHI; right to file complaints; rights to higher levels of protection for certain sensitive information);
>
> (ii) Procedures for the exercise of such rights (e.g., notice of privacy practices requirements, authorization requirements, de-identification processes, etc.); and
>
> (iii) Permitted and required uses and disclosures of PHI (e.g., uses and disclosures for treatment, payment, and health care operations, law enforcement activities, research purposes, etc.).

It is worth noting that Congress has had over twenty-five years to change course and enact federal privacy legislation or take other action if it found that HHS had exceeded its statutory authority by promulgating the Privacy Rule and its various amendments. Congress never challenged the validity of the Privacy Rule. Accordingly, it is reasonable to conclude that HHS acted within the scope of its delegated authority under HIPAA, and consistent with congressional intent when promulgating the Privacy Rule and its various amendments, including the 2024 Final Rule.

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[10] *See* Off. of Civ. Rts., *supra* note 3.

[11] Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82462 (Dec. 28, 2000) (codified at 45 C.F.R. §§ 160, 164).

[12] Standards for Privacy of Individually Identifiable Health Information, 67 Fed. Reg. 53182 (Aug. 14, 2002) (amending 45 C.F.R. §§ 160, 164).

B. The HIPAA Privacy Rule Was Enacted to Protect Private Health Information While Allowing the Flow of Information Necessary to Support Public Health

In drafting the Privacy Rule, HHS considered Congress's recognition of "the importance of protecting the privacy of health information given the rapid evolution of health information systems in . . . [HIPAA]" as well as "the challenges to the confidentiality of health information presented by the increasing complexity of the health care industry, and by advances in the health information systems technology and communications."[13] To address these challenges, Congress called for the enactment of the Privacy Rule to improve "the efficiency and effectiveness of the health care system by encouraging the development of a health information system through the establishment of standards and requirements for the electronic transmission of certain health information."[14] Congress created a federal overlay to protect the privacy of health information and guarantee patient access to such information. The reason was plain enough. HHS noted that "[r]ules requiring the protection of health privacy in the United States have been enacted primarily by the states" and that "these laws vary significantly from state to state and typically apply to only part of the health care system."[15] The Privacy Rule thus established, for the first time, "a set of basic national privacy standards and fair information practices to provide all Americans with a basic level of protection and peace of mind [] essential to their full participation in their care."[16] HHS intentionally and deliberately "set a floor of ground rules for health care providers, health plans, and health care clearinghouses to follow, in order to protect patients and encourage them to seek needed care," with the goal of balancing the needs of the individual with the needs of society

[13] *Id.* at 53182.
[14] Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. at 82462.
[15] *Id.* at 82463.
[16] *Id.* at 82464.

at large.[17] In developing a set of rules to achieve this stated goal, HHS also took direction from the Supreme Court's rulings establishing a fundamental privacy interest in personal medical information.[18] The preamble to the Privacy Rule and the regulations that were ultimately adopted clearly reflect HHS's measured approach to developing a workable framework that ensured sufficient access to health information for legitimate and important purposes, while also protecting individual privacy interests.

As acknowledged by Congress, one factor that particularly drove the need for national privacy standards was the transformation from paper to electronic medical records. The disclosure of sensitive information now required only the push of a button.[19] But that instant exchange also led to significant advances in the health care sector, including: (1) increasing the speed of the delivery of effective care and processing of billions of dollars' worth of health care claims, (2) advancing the ability to identify and treat those who are at risk for disease, conduct vital research, detect fraud and abuse, and measure and improve the quality of care, and (3) enhancing communications and improving access to information for health care providers, patients, health plan administrators, public health officials, biomedical researchers, and other health care professionals.[20]

As for improving the quality of health care, HHS recognized that "the entire health care system is built upon the willingness of individuals to share the most intimate details of their lives with their health care providers" and that "the relationship between a patient and clinician is based

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[17] *Id.*

[18] *See id.* ("Many of the most basic protections in the Constitution of the United States are imbued with an attempt to protect individual privacy while balancing it against the larger social purposes of the nation."); *see also Whalen v. Roe*, 429 U.S. 589, 599 (1977)(recognizing an "individual interest in avoiding disclosure of personal matters," and specifically, medical information).

[19] *See id.* at 82465.

[20] *See id.*

on trust."[21] With respect to privacy, HHS also noted that "patients who are worried about the possible misuse of their information often take steps to protect their privacy" and are less likely to participate fully in the diagnosis and treatment of their medical conditions, thereby impeding the goals of providing access to health care to all.[22] The final regulations balanced these interests.

In addition, Congress also recognized "the important role that health records play in conducting health research and wanted to ensure that implementation of the HIPAA Privacy Rule would not impede researchers' continued access to such data."[23] This is made clear in two contemporaneous House Reports that highlighted the issue:

> The conferees recognize that certain uses of individually identifiable information are appropriate, and do not compromise the privacy of an individual. Examples of such use of information include . . . the transfer of information from a health plan to an organization for the sole purpose of conducting health care-related research. As health plans and providers continue to focus on outcomes research and innovation, it is important that the exchange and aggregated use of health care data be allowed.[24]

Thus, HHS attempted to create a system that mandated privacy protection for individually identifiable health information, while allowing for the use of such information to facilitate health care and research in certain circumstances. In doing so, HHS recognized that research participants are more willing to share personal information and answer questions truthfully—thus fostering accurate and comprehensive data for research—when they are confident their privacy interests are protected, particularly against inadvertent or unwanted disclosure.[25]

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[21] *Id.* at 82467.

[22] *Id.* at 82468.

[23] SHARYL J. NASS, ET AL., NAT'L ACAD. OF SCIS., BEYOND THE HIPAA PRIVACY RULE: ENHANCING PRIVACY, IMPROVING HEALTH THROUGH RESEARCH 21 (2009), *available at* https://aisp.upenn.edu/wp-content/uploads/2015/03/BeyondHIPAAPrivacyRule_EnhancingPrivacy_ImprovingHealthThroughResearch_2009.pdf.

[24] H.R. REP. NO. 104-736, at 265 (1996) (Conf. Rep.). *See also* H.R. REP. NO. 104-496, at 100.

[25] NASS, ET AL., *supra* note 20 at 65.

C. The 2024 Reproductive Rights Rule Speaks to a Specific Need to Address Privacy Rights with Respect to Reproductive Health

On April 26, 2024, HHS published the 2024 Final Rule, largely in response to the Supreme Court's decision in *Dobbs*. Because reproductive health impacts so many individuals, protecting these records specifically is essential to maintain patient privacy and the integrity of the health care the system.

The 2024 Final Rule defines reproductive health broadly as health care "that affects the health of the individual in all matters relating to the reproductive system and to its functions and processes."[26] It seeks to protect the privacy rights of all individuals, including, but not limited to the following examples: contraception, preconception screening and counseling, impotence treatment and counseling, management of pregnancy and pregnancy-related conditions (including spontaneous miscarriage), male and female fertility and infertility diagnosis and treatment, reproductive system cancers (testicular, prostate, penile, cervical, ovarian, uterine, breast, vaginal, and vulvar cancers), diagnosis and treatment of conditions that affect the reproductive system (i.e., perimenopause, menopause, endometriosis, adenomyosis), and other types of care and supplies used for the diagnosis and treatment of conditions related to the reproductive system.[27] In this manner, the definition of reproductive health care includes services ranging from prostate exams to abortion care.

The 2024 Final Rule makes clear that the privacy rights granted under HIPAA are applicable to ***all*** types of health care information, including reproductive health care, which impacts almost all women in the United States. Reproductive health care includes contraceptive services, counseling, prenatal care, post pregnancy care, pelvic exams, and in some instances, a

[26] HIPAA Rule To Support Reproductive Health Care Privacy, 82 Fed. Reg. 32976, 33005 (Apr. 26, 2024) (amending 45 C.F.R. §§ 160, 164).

[27] *See id*. at 33006.

safely performed abortion.[28] However, following *Dobbs*, millions of individuals' access to reproductive health care has been jeopardized and medical privacy relating to reproductive healthcare has come under scrutiny as well. The altered landscape for reproductive health care, including vast swaths of the country with near-total abortion bans, has intensified an environment of fear for patients that they will be criminalized or scrutinized for their reproductive health care decisions and outcomes. This results in delays in patients seeking health care and information for their pregnancies, which cause worse outcomes for patients and concerns regarding up-to-date medical records, particularly if patients fear criminalization.

The patient-clinician relationship is a critical component of the provision of the highest quality health care and any efforts interfering with this relationship—including what is shared in medical records—harm the people seeking essential health care and those providing it.[29] The protections afforded by the 2024 Final Rule are necessary to enable health care providers to maintain their paramount role of protecting patient safety and to protect the sanctity of the patient-physician relationship in the area of reproductive health care.

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[28] *See, e.g.*, JENNIFER J. FROST, ET AL., GUTTMACHER, TRENDS AND DIFFERENTIALS IN RECEIPT OF SEXUAL AND REPRODUCTIVE HEALTH SERVICES IN THE UNITED STATES: SERVICES RECEIVED AND SOURCES OF CARE, 2006-2019 4 (2021), *available at* https://www.guttmacher.org/report/sexual-reproductive-health-services-in-us-sources-care-2006-2019; Jones & Jerman, *supra* note 30, at 1284. *See generally* Comm. on Reproductive Health Servs., The Safety and Quality of Abortion Care in the United States (2018), *available at* http://www.nap.edu/catalog/24950/the-safety-and-quality-of-abortion-care-in-the-united-states; *see also* Jones & Jerma, *supra* note 31; CDC, Abortion Surveillance – United States, 2015, Morbidity and Mortality Weekly Rep. Nov. 23, 2018, at 1, *available at* https://www.cdc.gov/mmwr/volumes/67/ss/pdfs/ss6713a1-H.pdf. *See also*, Ushma D. Upadhyay, et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 125 Obstetrics & Gynecology 175 (2015), *available at* https://escholarship.org/uc/item/523956jn.

[29] *See* AMA, *supra* note 36 ("The relationship between a patient and a physician is based on trust, which gives rise to the physicians' ethical responsibility to place patients' welfare above the physician's own self-interest of obligations to others, to use sound medical judgment on patients' behalf, and to advocate for their patients' welfare.").

Plaintiffs nevertheless take aim at the 2024 Final Rule and one of their primary contentions is that it restricts the ability of Plaintiffs and other health care providers to comply with state law reporting obligations and disclosure requirements regarding suspected abuse, neglect, or exploitation of vulnerable persons or violations of state law.[30] These assertions are misdirected. The 2024 Final Rule and the Privacy Rule contain explicit exceptions permitting such disclosures. For that matter, nothing in the 2024 Final Rule interferes with Plaintiffs' or any other health care provider's ability to report public health statistics to public health agencies or suspected abuse to government authorities. Simply put, Plaintiffs and other health care providers are not prohibited from making such disclosures, as long as the recipient provides an attestation that the information will not be used for a prohibited purpose—i.e., (i) investigating or imposing liability on a person for the mere act of seeking, obtaining, providing, or facilitating lawful reproductive health care, or (ii) investigating or imposing liability on a person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care that was lawful.

Plaintiffs also contend that the 2024 Final Rule puts the burden on Plaintiffs and other health care providers to make "legal judgments about whether any given instance of 'reproductive health care' was performed lawfully . . . ."[31] But this assertion is more misdirection. Notwithstanding the requirements under the 2024 Final Rule, Plaintiffs are already required to make those same legal judgments when assessing whether a patient's conduct or other information needs to be reported to state authorities in accordance with obligations to report abuse, neglect, exploitation, or other violations of state law against her legal and ethical obligations to keep patient information privileged and confidential. Similarly, physicians and other health care providers are

[30] *See* ECF 1 (Complaint) at 83-93.

[31] *See id.* at ¶ 95.

often already obligated to assess the legality of health care services. Using abortion services as an example, Texas law broadly prohibits abortion services, except for those abortions performed by a licensed physician, who has determined "in the exercise of reasonable medical judgment" that the abortion is necessary to prevent death or serious risk of substantial impairment of a major bodily function. Tex. Health & Safety Code § 170A.002(b). Texas law explicitly puts the onus on the physician to determine whether the abortion is "legal" under Texas' abortion ban. The 2024 Final Rule does not impose additional burdens.

II. THE HIPAA PRIVACY RULE PROVIDES A CONSISTENT AND RELIABLE FRAMEWORK REGULATING THE USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION

Since its enactment nearly three decades ago, the Privacy Rule has played a critical role in the American health care system. The 2024 Final Rule adds further essential protections specifically with respect to reproductive health care. Covered Entities rely upon the Privacy Rule, as amended by the 2024 Final Rule, to govern what information must be protected and what information, under what circumstances, may be shared. The Privacy Rule ensures that PHI is secure from disclosure, while balancing the need to share certain information for purposes of patient care and to allow health care providers to receive reimbursement for health care services, essential medical research, and to further public health. Without the Privacy Rule, as amended by the 2024 Final Rule, Covered Entities would have no direction regarding what information can be shared and when. The result would be either a chaotic flow of PHI, in violation of patients' rights and expectations, or a lockdown of medical records, resulting in stalled and incomplete medical care and research—or both.

HIPAA's facilitation of the transfer from paper to electronic medical records "helped to streamline administrative health care functions, improve efficiency in the health care industry, and

ensure that Protected Health Information is shared securely."[32] Additionally, HIPAA's adoption of uniform code sets and nationally recognized identifiers "help[ed] enormously with the transfer of electronic health information between health care providers, health plans, and other entities[]" while maintaining patients' privacy.[33] This also means that patients need not have gaps in their medical care, or be forced to repeat invasive and expensive tests, because they can easily have their medical information shared between providers.[34]

While electronic health record ("EHR") systems were available prior to the enactment of HIPAA in 1996, their use was primarily limited to large academic health systems. Moreover, the lack of standardized data elements and interfaces made data sharing between different providers and institutions complicated and cumbersome, and raised significant concerns with respect to data quality, privacy and security, patient informed consent and access issues, and data ownership/liability.[35] HIPAA's standardization of electronic health information and data sharing frameworks and HHS's regulations incentivizing the use of EHRs has since resulted in the widespread use of these systems. Based on data from the Assistant Secretary for Technology Policy/National Coordinator for Health IT, over 96% of hospitals and 78% of office-based

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[32] Steve Alder, *Why is HIPAA Important?*, THE HIPAA J. (Jan 10, 2025), https://www.hipaajournal.com/why-is-hipaa-important/#:~:text=HIPAA%20helps%20to%20ensure%20that,who%20it%20is%20shared%20with.

[33] *Id.*

[34] *Id.*

[35] R. S. Evans, *Electronic Health Records: Then, Now, and in the Future*, IMIA Y.B. OF MED. INFORMATICS, 2016, S48, S48 (2016), *available at* https://www.thieme-connect.com/products/ejournals/pdf/10.15265/IYS-2016-s006.pdf.

physicians have adopted an EHR as of 2021, compared to much lower rates at the time HIPAA was adopted.[36]

Under HIPAA, PHI can be shared without a patient's written authorization, and without the need to provide the patient an opportunity to object to the disclosure, for certain enumerated purposes (with some conditions).[37] These permitted disclosures include, among other things, disclosures required by law, disclosures for public health activities (e.g., reporting diseases, births, and deaths, public health investigations, etc.), disclosures about victims of abuse, neglect, or domestic violence, disclosures for health oversight activities (e.g., criminal investigations, licensure or disciplinary actions, etc.), disclosures for law enforcement purposes, disclosures for organ, eye, or tissue donations, and disclosures for medical research.[38] These provisions facilitate necessary data sharing to support public health and safety activities, ensure that HIPAA is not inappropriately used as a shield for illegal conduct, and serve to foster critical medical research and innovation. "Health research is vital to improving human health and health care—and protecting individuals involved in research from harm and preserving their rights is essential to the conduct of ethical research."[39] Importantly, medical research fosters life-saving innovations, including vaccines, therapies, diagnostics, "and more effective ways to prevent illness and deliver care."[40] This careful balancing of parallel interests—sharing certain PHI for specified and

[36] Off. of the Nat'l Coordinator for Health Info. Tech., *Adoption of Electronic Health Records by Hospital Service Type 2019-2021*, ASTP, https://www.healthit.gov/data/quickstats/adoption-electronic-health-records-hospital-service-type-2019-2021 (last visited Mar. 6, 2025).

[37] 45 C.F.R. § 164.512.

[38] HHS, SUMMARY OF THE HIPAA PRIVACY RULE 4-8 (2003), *available at* https://www.hhs.gov/sites/default/files/privacysummary.pdf.

[39] NASS, ET AL., *supra* note 20 at 15.

[40] *Id*.

approved health research to benefit society while valuing privacy interests—is an essential component of the existing federal privacy landscape.

The HIPAA Privacy Rule has continuously evolved, through the legislative and regulatory process, in response to health care needs nationwide. For example, the Health Information Technology for Economic and Clinical Health ("HITECH") Act is part of the American Recovery and Reinvestment Act of 2009, which "incentivized the meaningful use of [electronic health records] and strengthened privacy and security provisions of HIPAA."[41] Pursuant to the updated requirements under HITECH, HHS promulgated updated privacy regulations in 2013 in its Final Omnibus Rule based on public comment to its Interim Omnibus Rule.[42] These changes reflected changes in the industry necessitating a rebalancing of privacy interests in access/use interests. For example, HITECH and its implementing regulations expanded upon prior rules to facilitate medical research to permit a HIPAA authorization to be used for disclosures for future research "if the authorization adequately describes the future research such that it would be reasonable for an individual to expect that his or her protected health information could be used or disclosed for that purpose."[43] This means that authorizations no longer needed to be study-specific, provided the required information was disclosed to research participants, which reflects HHS's efforts to reasonably balance the privacy interests of the individual in light of changes to the larger health care system.

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[41] Steve Alder, *What is the HITECH Act?*, THE HIPAA J. (Jan. 2, 2025), https://www.hipaajournal.com/what-is-the-hitech-act/.

[42] Liam Johnson, *Why is the HITECH Act Important?*, THE HIPAA GUIDE (Dec. 12, 2023), https://www.hipaaguide.net/why-is-the-hitech-act-important/.

[43] SHARYL J. NASS & MARGIE PATLAK, NAT'L ACAD. OF SCIS., CONTEMPORARY ISSUES FOR PROTECTING PATIENTS IN CANCER RESEARCH 25 (2014), *available at* https://www.ncbi.nlm.nih.gov/books/NBK247001/.

Furthermore, as technology continues to evolve with the advent of artificial intelligence ("AI"), so will the HIPAA Privacy Rule. Taking it a step further, it is HIPAA that will pave the way for the development of AI and other technological advancements in the health care industry. Indeed, HHS recently released its AI Strategic Plan to foster innovation and the adoption of "responsible AI to achieve unparalleled advances in the health and well-being of all Americans."[44] The plan "provides a framework and roadmap to ensure that HHS fulfills its obligation to the Nation and pioneers the responsible use of AI to improve people's lives."[45] Technologies such as AI "are making it even more possible to predict diseases before symptoms appear, identify new drug targets with the potential to transform the standard of care, and more effectively match human services to people who need them most."[46] Just as the transition from paper to electronic records came with risks, so, too, does the transition to utilization of technological advances such as AI. HHS recognized that "[m]aximizing opportunities and mitigating risks is core to HHS's long-standing mission: Enhance the health and well-being of all Americans by supporting effective health and human services and fostering sound, sustained advances in the sciences underlying medicine, public health, and social services."[47] As Covered Entities determine how to proceed ethically in this new landscape, they will look, as they have for decades, to HIPAA for guidance in building appropriate frameworks for growth and compliance.

While the above only skims the surface of the far-reaching benefits of the HIPAA Privacy Rule, one thing is abundantly clear: they constitute a longstanding, evolving framework of rules

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[44] HHS, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES: STRATEGIC PLAN FOR THE USE OF ARTIFICIAL INTELLIGENCE IN HEALTH, HUMAN SERVICES, AND PUBLIC HEALTH 6 (2025), *available at* https://digitalgovernmenthub.org/wp-content/uploads/2025/02/2025-HHS-AI-Strategic-Plan_Full_508.pdf.

[45] *Id.*

[46] *Id.*

[47] *Id.* at 7.

that provide certainty and consistency across all Covered Entities nationwide to strike the balance between individual privacy and data sharing for the good of society and medical innovation. The 2024 Final Rule is another piece of this evolving framework.

III. INVALIDATING THE HIPAA PRIVACY RULE OR THE 2024 FINAL RULE WOULD LEAD TO A DATA LOCKDOWN, STALLING ESSENTIAL MEDICAL RESEARCH AND INNOVATION AND UNDERMINING ESSENTIAL PATIENT CARE

For decades, the HIPAA Privacy Rule has existed and evolved to respond to and support the health care industry nationwide. Many states have enacted their own consumer protection laws, but those laws include carveouts or exceptions for data already governed by HIPAA. There is good reason for that: the HIPAA Privacy Rule adequately and rigorously protects consumer information, as conceded by those states when they wrote those laws—Texas included.

On June 18, 2023 (23 years after HHS promulgated the original HIPAA Privacy Rule at the behest of Congress), Governor Greg Abbott signed the Texas Data Privacy and Security Act ("TDPSA") into law, which became effective on July 1, 2024.[48] The TDSPA exempts certain entities, including those covered by HIPAA. Even further, it exempts certain types of information, including information covered by HIPAA. The same goes for the Texas Health and Safety Code.[49] But irrespective of Texas privacy rules, none of the state laws offer the groundwork for a consistent approach in place of the longstanding, time-tested, and well-understood HIPAA Privacy Rule. Even worse, taken together they lead to inconsistent and conflicting results.

In that void, there are three obvious, non-exhaustive, consequences.

First, there is a serious risk that data sharing premised on HIPAA compliance will stop entirely until that gap is (presumably) filled by state laws. Moreover, there is no guarantee that

[48] Tex. Bus. & Com. Code Ann. § 541.001 et seq.

[49] *See, e.g.*, Tex. Health & Saf. Code § 181.001(a).

such state laws would be remotely consistent with one another—in fact, with no overarching framework, it is all but guaranteed that such state laws would conflict in ways that would have a stifling effect on the ability to share PHI. For example, key definitions within state laws may differ in ways that make compliance, particularly with respect to the sharing of data across state lines, impossible.

Second, there is a serious risk that without the HIPAA framework and enforcement backstop for noncompliance, PHI may be shared inappropriately, which unauthorized acquisition, access, use, or disclosure of PHI is presumed to be a breach under federal law that is not subject to this litigation. In that case, there is also risk that the public's trust in the health care system and their health care providers would be substantially eroded. Patients may be fearful of obtaining necessary, and in some cases lifesaving, medical treatment, or of simply being fully forthcoming with their health care providers, which may also jeopardize the health care they receive and their outcomes.

Third, the critical guardrails governing data sharing that permit essential medical research and innovation will be torn apart with nothing left in its place except a random assortment of state privacy laws with exemptions for HIPAA Covered Entities and PHI that no longer make sense in the absence of HIPAA. Shared data would be disseminated according to no consistent framework, thus impacting the integrity of any medical research—ultimately hurting all Americans as medical innovation becomes stifled.[50]

[50] Sharona Hoffman & Andy Podgurski, *Balancing Privacy, Autonomy, and Scientific Needs in Electronic Health Records Research*, 65 SMU L. REV. 85, 85 (2012) (the "potential to catalyze significant advances in medical knowledge[]" is only possible "if the data available to researchers is representative of the patient population as a whole").

Plaintiffs—and the Texas Attorney General, in his parallel suit[51]—ask this Court to issue an injunction invalidating the HIPAA Privacy Rule and the 2024 Final Rule amending the Privacy Rule despite the fact that the rules offer a clear and consistent structure that balances medical privacy and information sharing with the betterment of health care delivery and improvement of public health. The proposed invalidation is unwarranted, unwise, and unnecessary given existing legislative accommodations. Amici's Hippocratic oath provides that doing no harm is the ethical and laudable course. The denial of the requested injunction fulfills that goal here.

CONCLUSION

Amici urge this Court to deny the broad, disproportionate relief sought. Any changes to the existing HIPAA regulations or enactment of new health care privacy laws should be accomplished thorough the legislative process that incorporates public comment from industry, including Amici and Plaintiffs.

Dated this the 10th day of March, 2025.

/s/ James C. Martin

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[51] *See State of Texas v. U.S. Dept. of Health & Human Services*, 5:24-cv-00204-H, ECF No. 1 (N.D. Tex. filed Sept. 4, 2024).

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